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510(k) SUMMARY
Product Name: V.A.C. Freedom® and V.A.C. ATS® Therapy Device Canisters

Date prepared	November 30, 2006
510(k) Owner **Name** **Address** **Fax number**	 KCI USA, Inc. 8023 Vantage Dr., San Antonio, TX 78230 (210) 255-6727
Name of contact person	Christy Hubbard Oviatt, Sr. Regulatory Affairs Specialist
Name of the device **Trade or proprietary name** **Common or usual name** **Classification name**	• V.A.C. 300 ml Canister (with Gel) for V.A.C. Freedom® • 500 ml Canister (with Gel) for V.A.C. ATS® • 500 ml Canister for V.A.C. ATS® Accessory to Negative Pressure Wound Therapy Device Accessory to Powered Suction Pump
Legally marketed device to which equivalence is claimed	The canisters are proposed to be substantially equivalent to canisters currently marketed in sterile barrier packaging. These canisters were included in the V.A.C. Family of Devices 510(k) K032310. • V.A.C. 300 ml Canister (with Gel) for V.A.C. Freedom® • 500 ml Canister (with Gel) for V.A.C. ATS® • 500 ml Canister for V.A.C. ATS®
Device description **Device function** **Device design**	The V.A.C. ATS® and V.A.C. Freedom® canisters are provided with a sterile fluid path for single use with the V.A.C. ATS® and V.A.C. Freedom® therapy units. The V.A.C. ATS® and V.A.C. Freedom® canisters function as reservoirs to collect fluids and wound exudates removed from the wounds during treatment with the negative pressure therapy devices. The canisters are molded plastic devices designed to insert into the V.A.C. Freedom® or V.A.C. ATS® Therapy units.

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Differences in device design from predicate device	The only difference between the proposed and the predicate devices is the means by which sterility of the fluid path of the device is maintained. The predicate products are packaged with sterile barrier packaging while the modified canisters are designed with sterile barriers at the open ends of the fluid path of the product to maintain the sterility prior to use.
Intended use of the device **Differences in intended use from the predicate**	The V.A.C. Therapy System is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The V.A.C.® GranuFoam® Silver™ Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types. The intended use of the devices has not changed from the intended use of the predicate devices.
Summary of the technological characteristics of the device	The modified and unmodified V.A.C. ATS® and V.A.C. Freedom® canisters have molded-in graduation markings on the side of the canister to aid in estimation of fluid removal. Hydrophobic membranes secured to the side of the canisters during the manufacturing process isolate the collected fluid from the vacuum pump in each case. A gel packet is included in the V.A.C. Freedom® canister and in one model of the V.A.C. ATS® canisters to solidify the wound fluid in the canister.
Summary of nonclinical tests	Verification of the integrity of the fluid path sterile barriers of the modified design was through accelerated aging, distribution simulation, and microbial aerosol challenge testing.
Conclusions drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device	The modified V.A.C. ATS® and V.A.C. Freedom® canisters with the sterile fluid path are safe and effective for their intended use. The sterility assurance level of the sterile fluid path of the canisters can be assured to a level of 10^{-6}.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

KCI USA, Inc.
% Ms. Christy Oviatt
6203 Farinon Drive
San Antonio, Texas 78230

Re: K063590
Trade/Device Name: V.A.C.® Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: January 4, 2007
Received: January 5, 2007

Dear Ms. Oviatt:

This letter corrects our substantially equivalent letter of January 25, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K063590
Device Name: V.A.C.® Therapy System
Indications for Use:

The V.A.C. Therapy System is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

The V.A.C.® GranuFoam® Silver™ Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, I
and Neurological Dev

510(k) Number K063590